

105TH CONGRESS
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H. R. 1710

To amend the Federal Food, Drug, and Cosmetic Act to facilitate the development, clearance, and use of devices to maintain and improve the public health and quality of life of the citizens of the United States.

IN THE HOUSE OF REPRESENTATIVES

MAY 22, 1997

Mr. BARTON of Texas (for himself, Ms. ESHOO, Mr. BLILEY, Mr. BILIRAKIS, Mr. GREENWOOD, Mr. DAN SCHAEFER of Colorado, Mr. HALL of Texas, Mr. HASTERT, Mr. MANTON, Mr. TAUZIN, Mr. TOWNS, Mr. OXLEY, Ms. FURSE, Mr. UPTON, Mr. RUSH, Mr. STEARNS, Mr. PAXON, Mr. GILLMOR, Mr. KLUG, Mr. CRAPO, Mr. COX of California, Mr. DEAL of Georgia, Mr. LARGENT, Mr. BURR of North Carolina, Mr. BILBRAY, Mr. WHITFIELD, Mr. GANSKE, Mr. NORWOOD, Mr. WHITE, Mr. COBURN, Mr. LAZIO of New York, Mrs. CUBIN, Mr. ROGAN, Mr. SHIMKUS, Mr. GORDON, Mr. EHRLICH, Mr. RAMSTAD, Mr. WYNN, Ms. MCCARTHY of Missouri, and Mr. PALLONE) introduced the following bill; which was referred to the Committee on Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to facilitate the development, clearance, and use of devices to maintain and improve the public health and quality of life of the citizens of the United States.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE; REFERENCE; TABLE OF CON-**
 2 **TENTS.**

3 (a) **SHORT TITLE.**—This Act may be cited as the
 4 “Medical Device Regulatory Modernization Act of 1997”.

5 (b) **REFERENCE.**—Whenever in this Act an amend-
 6 ment or repeal is expressed in terms of an amendment
 7 to, or repeal of, a section or other provision, the reference
 8 shall be considered to be made to that section or other
 9 provision of the Federal Food, Drug, and Cosmetic Act
 10 (21 U.S.C. 301 et seq.).

11 (c) **TABLE OF CONTENTS.**—The table of contents is
 12 as follows:

- Sec. 1. Short title; reference; table of contents.
- Sec. 2. FDA mission and annual report.
- Sec. 3. Dispute resolution.
- Sec. 4. Investigational device exemptions.
- Sec. 5. Special review for certain devices.
- Sec. 6. Expanding humanitarian use of devices.
- Sec. 7. Performance standards.
- Sec. 8. Scope of review.
- Sec. 9. Premarket notification.
- Sec. 10. Classification panels.
- Sec. 11. Premarket approval.
- Sec. 12. Accreditation for accredited persons.
- Sec. 13. Preamendment devices.
- Sec. 14. Device tracking.
- Sec. 15. Postmarket surveillance.
- Sec. 16. Harmonization.
- Sec. 17. Reports.
- Sec. 18. G.M.P. and device reports.
- Sec. 19. Information system.
- Sec. 20. Environmental impact review.
- Sec. 21. Practice of medicine.
- Sec. 22. Publication of notice of deviation.

13 **SEC. 2. FDA MISSION AND ANNUAL REPORT.**

14 (a) **MISSION.**—Section 903 (21 U.S.C. 393) is
 15 amended by redesignating subsections (b) and (c) as sub-

1 sections (c) and (d), respectively, and by adding after sub-
2 section (a) the following:

3 “(b) MISSION.—The Food and Drug Administration
4 shall protect the public health by ensuring that—

5 “(1) foods are safe, wholesome, and sanitary;

6 “(2) there is a reasonable assurance that
7 human and veterinary drugs and devices are safe
8 and effective;

9 “(3) cosmetics are safe; and

10 “(4) public health and safety are protected
11 from electronic product radiation.

12 The Food and Drug Administration shall promptly and
13 efficiently review clinical research and take appropriate ac-
14 tion on the marketing of regulated products in a manner
15 that does not unduly impede innovation or product avail-
16 ability. The Food and Drug Administration shall partici-
17 pate with other countries to reduce the burden of regula-
18 tion, harmonize regulatory requirements, and achieve ap-
19 propriate reciprocal arrangements.”.

20 (b) ANNUAL REPORT.—Section 903 (21 U.S.C. 393),
21 as amended by subsection (a), is amended by adding at
22 the end the following:

23 “(e) ANNUAL REPORT.—The Secretary shall, simul-
24 taneously with the submission each year of the budget for
25 the Food and Drug Administration, submit to the Com-

1 mittee on Commerce of the House of Representatives and
2 the Committee on Labor and Human Resources of the
3 Senate an annual report which shall—

4 “(1) review the performance of the Food and
5 Drug Administration in meeting its mission and the
6 development of Food and Drug Administration poli-
7 cies to implement such mission;

8 “(2) review the performance of the Food and
9 Drug Administration in meeting its own perform-
10 ance standards, including its own outcome measure-
11 ments and statutory deadlines for the approval of
12 products or for other purposes contained in this Act;

13 “(3) describe the staffing and resources of the
14 Food and Drug Administration and list those per-
15 sons and organizations accredited to conduct initial
16 classification of devices under section 513; and

17 “(4) describe the goals, activities, and accom-
18 plishments of the Food and Drug Administration in
19 bilateral and multinational meetings that addressed
20 methods and approaches to reduce the burden of
21 regulation, harmonize regulatory requirements, and
22 to seek appropriate reciprocal arrangements.

23 “(f) GAO ANNUAL REPORT.—The Comptroller Gen-
24 eral of the United States shall each January submit to
25 the Committee on Commerce of the House of Representa-

1 tives and the Committee on Labor and Human Resources
2 of the Senate a report which compares—

3 “(1) the performance of the Food and Drug
4 Administration in approving innovative drug, device,
5 and food products with that of agencies performing
6 similar functions in countries listed in section
7 802(b); and

8 “(2) the resources used by agencies in such
9 countries to approve such products.

10 In developing a methodology for the report, the Comptrol-
11 ler General shall consult with representatives of the Sec-
12 retary, the regulated industry, academic experts in the
13 field, and experts knowledgeable about information in such
14 other countries so that the approach accurately presents
15 the information in a fair and balanced manner.”.

16 **SEC. 3. DISPUTE RESOLUTION.**

17 (a) AMENDMENT.—Chapter V is amended by adding
18 after section 522 the following:

19 “DISPUTE RESOLUTION

20 “SEC. 523. In instances in which there is a scientific
21 controversy between a regulated person and the Secretary
22 regarding an obligation under this Act and no specific pro-
23 vision of this Act or regulations promulgated under this
24 Act by the Secretary provide a right to review of the sub-
25 ject matter in dispute, the Secretary shall by regulation
26 establish a procedure under which a regulated person may

1 request such a review and such a review shall be provided
2 in a timely manner.”.

3 (b) REGULATIONS.—The Secretary of Health and
4 Human Services shall promulgate regulations implement-
5 ing section 523 of the Federal Food, Drug, and Cosmetic
6 Act within 180 days of the date of the enactment of this
7 Act.

8 **SEC. 4. INVESTIGATIONAL DEVICE EXEMPTIONS.**

9 Section 520(g) (21 U.S.C. 360j(g)) is amended by
10 adding at the end the following:

11 “(6) The Secretary shall, by regulation and within
12 120 days of the date of the enactment of this paragraph,
13 update the procedures and conditions under which devices
14 intended for human use may upon application be granted
15 an exemption from certain requirements of this Act. Such
16 regulation shall—

17 “(A) define the parameters for the use of inves-
18 tigational devices for the benefit of individual pa-
19 tients, outside of an ongoing investigational protocol
20 (but subject to the patient protections incorporated
21 into part 812 or 813 of title 21, Code of Federal
22 Regulations), during the pendency of a premarket
23 approval application under section 515 and for uses
24 intended to demonstrate a reasonable assurance of a
25 device’s safety or effectiveness in the diagnosis or

1 treatment of diseases or conditions that are life-
2 threatening or could be irreversibly debilitating,
3 when (i) the treating physician determines that the
4 investigational device likely will provide a benefit, (ii)
5 the risk of not using the investigational device ex-
6 ceeds the probable risk of using such device, and (iii)
7 there is no legally marketed device alternative for
8 the satisfactory treatment or diagnosis of such dis-
9 ease or condition;

10 “(B) ensure that prior to submitting an appli-
11 cation to the Secretary or to an institutional review
12 board, any person intending to investigate the safety
13 or effectiveness of a class III device or an implant
14 device will have the opportunity to submit an inves-
15 tigational plan, including a clinical protocol, to the
16 Secretary for review;

17 “(C) within 30 days of a request by an appli-
18 cant for a meeting with the Secretary, require, un-
19 less the applicant waives this subparagraph, the Sec-
20 retary to meet with the applicant; and

21 “(D) permit developmental changes in devices
22 in response to information gathered during the
23 course of an investigation without requiring an addi-
24 tional approval of an application for an investiga-
25 tional device exemption or the approval of a supple-

1 ment to such an application, if such changes do not
2 constitute a significant change in design or a signifi-
3 cant change in basic principles of operation;

4 “(E) without additional approval of an applica-
5 tion for an investigational device exemption, or the
6 approval of a supplement to such an application,
7 permit changes or modifications to clinical protocols
8 that do not affect the validity of data or information
9 resulting from the completion of an approved proto-
10 col and do not alter the relationship of likely patient
11 risk to benefit relied upon to approve a protocol; and

12 “(F) require a notice to the Secretary within 5
13 days of implementing any change pursuant to sub-
14 paragraph (D) or (E).

15 Any dispute arising from a change under subparagraph
16 (D) or (E) shall be resolved under section 523(b).”.

17 **SEC. 5. SPECIAL REVIEW FOR CERTAIN DEVICES.**

18 Section 515(d) (21 U.S.C. 360e(d)) is amended by
19 adding at the end the following:

20 “(4) In order to better treat or diagnose life-threaten-
21 ing or irreversibly debilitating human diseases or condi-
22 tions, the Secretary shall promulgate a regulation to cre-
23 ate review priority for devices—

24 “(A) representing breakthrough technologies,

25 “(B) for which no approved alternatives exist,

1 “(C) which offer significant advantages over ex-
2 isting approved alternatives, or

3 “(D) the availability of which is in the best in-
4 terest of the public health.

5 Such regulation shall include, among other things, criteria
6 identifying devices which merit preferential review, speci-
7 fying procedures for implementing such reviews, and iden-
8 tifying substantive review criteria appropriate to making
9 prompt and efficient review of such devices. The Secretary
10 shall publish in the Federal Register a proposed regulation
11 to create such review priority no later than 6 months after
12 the date of the enactment of this paragraph, allowing 60
13 days for comment. The Secretary will publish a final regu-
14 lation no later than 120 days after the last day of the
15 comment period.”.

16 **SEC. 6. EXPANDING HUMANITARIAN USE OF DEVICES.**

17 (a) SECTION 520(m).—Section 520(m) (21 U.S.C.
18 360j(m)) is amended—

19 (1) in paragraph (2), by inserting after and
20 below subparagraph (C) the following:

21 “The request shall be in the form of an application to the
22 Secretary. Within 60 days of the date of the receipt of
23 an application, the Secretary shall issue an order approv-
24 ing or denying the application, except that if the Secretary

1 convenes a scientific advisory panel, the Secretary may
2 have an additional 60 days in which to issue such order.”;

3 (2) by amending paragraph (5) to read as fol-
4 lows:

5 “(5) The Secretary may suspend or withdraw an ex-
6 emption from the effectiveness requirements of sections
7 514 and 515 for a humanitarian device, after providing
8 notice and an opportunity for an informal hearing, if any
9 condition for granting such exemption for such device set
10 forth in paragraphs (2) through (4) no longer is met.”;
11 and

12 (3) by striking paragraph (6).

13 (b) REGULATIONS.—Any regulation included in title
14 21 of the Code of Federal Regulations pertaining to hu-
15 manitarian devices which is inconsistent with the amend-
16 ments made by subsection (a) shall be deemed rescinded
17 on the date of the enactment of this Act. The Secretary
18 shall promulgate regulations pertaining to humanitarian
19 devices which are consistent with such amendments.

20 **SEC. 7. PERFORMANCE STANDARDS.**

21 (a) SECTION 514.—Section 514 (21 U.S.C. 360d) is
22 amended to read as follows:

23 “STANDARDS

24 “SEC. 514. (a) The Secretary shall, through publica-
25 tion in the Federal Register, issue notices identifying and
26 adopting applicable nationally or internationally recog-

1 nized consensus standards to which a person may self-cer-
2 tify compliance for the purpose of demonstrating a reason-
3 able assurance that a device is safe or effective or to deter-
4 mine compliance with any requirement of this Act. Any
5 person may elect to utilize data other than those required
6 by such standards to demonstrate a reasonable assurance
7 of device safety or effectiveness or compliance with the re-
8 quirements of this Act.

9 “(b) The Secretary shall accept certifications that de-
10 vices conform with each type of standard referenced in
11 subsection (a) and identified in each such certification to
12 the extent such standard applies, except that the Secretary
13 may, at any time, request the person who submitted the
14 certification to submit the data and information which
15 such person relied upon in making such certification.”.

16 (b) SECTION 301.—Section 301 (21 U.S.C. 331) is
17 amended by adding after paragraph (w) the following:

18 “(x) The making of a false or misleading certification
19 under section 514(b) or the failure or refusal to provide
20 the information required under section 514(c).”.

21 **SEC. 8. SCOPE OF REVIEW.**

22 (a) SECTION 513(a).—Section 513(a)(3) (21 U.S.C.
23 360c(a)(3)) is amended—

24 (1) in subparagraph (A), by inserting “one or
25 more” before “clinical investigations”;

1 (2) by adding at the end of subparagraph (A)
2 the following: “In determining the type and amount
3 of data necessary to find a reasonable assurance of
4 device effectiveness for an approval under section
5 515, the Secretary shall consider the extent to which
6 reliance on postmarket controls may contribute to
7 such assurance and expedite effectiveness determina-
8 tions without increasing regulatory burdens on per-
9 sons who submit applications under section 515(c).”;

10 (3) by adding at the end the following:

11 “(C)(i) The Secretary, upon the request of any per-
12 son intending to submit an application under section 515,
13 shall meet to determine the type of valid scientific evidence
14 within the meaning of subparagraphs (A) and (B) that
15 will be necessary to demonstrate the effectiveness of a de-
16 vice for the conditions of use proposed by such person to
17 support an approval of an application. Within 30 days of
18 such meeting, the Secretary shall identify in writing the
19 type of valid scientific evidence that will provide a reason-
20 able assurance that a device is effective under the condi-
21 tions of use proposed by such person. Any clinical data,
22 including one or more well-controlled investigations, speci-
23 fied by the Secretary for demonstrating a reasonable as-
24 surance of device effectiveness shall reflect the Secretary’s
25 determination that such data are necessary to establish

1 device effectiveness and that no other less burdensome
2 means of evaluating effectiveness are available that would
3 have a reasonable likelihood of resulting in an approval.

4 “(ii) The Secretary’s specification of the valid sci-
5 entific evidence under clause (i) shall be binding upon the
6 Secretary unless such determination by the Secretary
7 would be contrary to the public health.”.

8 (b) SECTION 513(i).—Section 513(i)(1) (21 U.S.C.
9 360e(i)(1)) is amended by adding at the end the following:

10 “(C) To facilitate reviews of reports submitted to the
11 Secretary under section 510(k), the Secretary shall con-
12 sider the extent to which reliance on postmarket controls
13 may expedite the classification of devices under subsection
14 (f)(1) of this section.

15 “(D) Whenever the Secretary requests information to
16 demonstrate that devices with differing technological char-
17 acteristics are substantially equivalent, the Secretary shall
18 only request information that is necessary to making sub-
19 stantial equivalence determinations. In making such re-
20 quest, the Secretary shall consider the least burdensome
21 means of demonstrating substantial equivalence and re-
22 quest information accordingly.

23 “(E) Any determinations of substantial equivalence
24 by the Secretary shall be based upon the labeling submit-
25 ted in a report under section 510(k) or labeling agreed

1 to between the Secretary and persons who submit such
2 report.

3 “(F) Representations in promotional materials shall
4 not require a report under section 510(k) unless such ma-
5 terials support or promote new intended uses of a legally
6 marketed device.”.

7 (c) SECTION 515(d).—Section 515(d) (21 U.S.C.
8 360e(d)) is amended—

9 (1) by adding at the end of paragraph (1)(A)
10 the following:

11 “The Secretary’s determination to approve or deny an ap-
12 plication shall be based on the conditions of use proposed
13 in labeling. If, based on a fair evaluation of all material
14 facts, the proposed labeling is neither false or misleading
15 in any particular, the Secretary shall not consider matters
16 outside of such labeling in disposing of the application.”;
17 and

18 (2) by adding after paragraph (4), as added by
19 section 5, the following:

20 “(5)(A) Supplemental applications shall be required
21 for any change to a device subject to an approved applica-
22 tion under this subsection which affects safety or effective-
23 ness and if a change was made under the requirements
24 of section 520(f), the holder of the approved application
25 shall notify the Secretary of such change.

1 “(B) When reviewing a supplement to an approved
2 application for an incremental change to the design of a
3 device that affects safety or effectiveness, the Secretary
4 shall approve such supplement when nonclinical data dem-
5 onstrate that a design modification achieves the intended
6 additional capacity, function, or performance without re-
7 ducing the safety or effectiveness of the device and, when
8 appropriate, clinical data in the approved application and
9 supplements thereto and clinical data specifically evaluat-
10 ing the design modification provide reasonable assurance
11 of device effectiveness.

12 “(6) Representations in promotional materials for de-
13 vices subject to approved applications under paragraph (1)
14 shall not be subject to premarket approval under this sec-
15 tion, unless such representations establish new conditions
16 of use. Any such representations must be supported by
17 appropriate substantiation materials in the application
18 holder’s possession at the time such representations are
19 made.”.

20 **SEC. 9. PREMARKET NOTIFICATION.**

21 (a) SECTION 510.—Section 510 (21 U.S.C. 360) is
22 amended—

23 (1) in subsection (k), by inserting after “a de-
24 vice intended for human use” the following: “(other
25 than any device classified into class I or II under

1 section 513 or 520 if such class II device has been
2 exempted from the requirements of this subsection
3 under subsection (l)");

4 (2) in subsection (k), by striking "report to the
5 Secretary" and inserting "have the option of report-
6 ing to the Secretary or any person who is not an em-
7 ployee of the United States and who is accredited
8 under section 712(a)";

9 (3) by adding after and below paragraph (2) of
10 subsection (k) the following:

11 "The accredited person shall review a report made to the
12 person and submit, not later than 60 days after receiving
13 the report, to the Secretary the person's recommendation
14 for action to be taken by the Secretary on the report.";
15 and

16 (4) by adding the following after subsection (k):

17 "(l) Within 30 days after the date of the enactment
18 of this subsection, the Secretary shall publish in the Fed-
19 eral Register a list of each type of class II device that
20 does not require a report under subsection (k) to provide
21 reasonable assurance of safety and effectiveness. Each
22 type of class II device listed by the Secretary shall be ex-
23 empt from the requirement to file a report under sub-
24 section (k) as of the date of the publication of the list
25 in the Federal Register. Beginning on the date that is 1

1 day after the date of the publication of the list, any person
2 may petition the Secretary to exempt a type of class II
3 device from the reporting requirement of subsection (k).
4 If the Secretary fails to respond to a petition within 120
5 days of receiving it, the petition shall be deemed to be
6 granted.”.

7 (b) REPORTS UNDER SECTION 510(k).—Class I de-
8 vices which are intended to be life supporting or life sus-
9 taining, intended for a use which is of substantial impor-
10 tance in preventing impairment of human health, or
11 present a potential unreasonable risk of illness or injury
12 shall not be excluded from the requirements of reports
13 under section 510(k) of the Federal Food, Drug, and Cos-
14 metic Act (21 U.S.C. 360(k)).

15 (c) INITIAL CLASSIFICATION.—Section 513(f) (21
16 U.S.C. 360c(f)) is amended—

17 (1) in the second sentence of paragraph (1) by
18 striking the period at the end and inserting the fol-
19 lowing: “unless within 30 days of receiving an order
20 classifying the device into class III the individual
21 who submits a report under section 510(k) for such
22 device requests review with respect to the classifica-
23 tion of the device and a final order of classification
24 from the Secretary. After the request, a device clas-
25 sified into class III under this paragraph shall not

1 be deemed to be finally classified until the Secretary
2 has determined the classification of the device based
3 on the classification criteria set forth in subpara-
4 graphs (A) through (C) of subsection (a)(1), within
5 60 days of receiving the request to review and clas-
6 sify a device. Any device found under this paragraph
7 not to be substantially equivalent to a device de-
8 scribed in subparagraph (A)(i) and which is classi-
9 fied by the Secretary into class III may not be com-
10 mercially distributed in commerce before it is ap-
11 proved under section 515.”; and

12 (2) by adding at the end the following:

13 “(4) The Secretary may not withhold a determination
14 of the initial classification of a device under paragraph (1)
15 because of a failure to comply with any provision of this
16 Act unrelated to a substantial equivalence decision, includ-
17 ing a finding that the facility in which the device is manu-
18 factured is not in compliance with good manufacturing re-
19 quirements as set forth in regulations of the Secretary
20 under section 520(f).”.

21 (d) SECTION 513(i).—Section 513(i) (21 U.S.C.
22 360c(i)), as amended by section 8(b), is amended—

23 (1) in paragraph (1)(A)(ii)(I), by striking “clin-
24 ical data” and inserting “appropriate clinical or sci-

1 entific data” and by inserting “or a person accred-
2 ited under section 712” after “Secretary”;

3 (2) in paragraph (1)(A)(ii)(II), by striking “ef-
4 ficacy” and inserting “effectiveness”; and

5 (3) by adding at the end of paragraph (1) the
6 following:

7 “(G) For purposes of subparagraph (A), the term ‘le-
8 gally marketed device’ includes any device introduced into
9 interstate commerce for commercial distribution before
10 May 28, 1976, and any device found substantially equiva-
11 lent to such device which has not been removed from the
12 market by an order of the Secretary or a judicial order
13 because it is unsafe or ineffective.

14 “(H) For the purpose of determining the intended
15 use of a predicate device under subparagraph (A), each
16 use reasonably included within a general use for the predi-
17 cate device shall be deemed a legally marketed use of the
18 predicate device and shall be available for use in pre-
19 market notifications required under section 510(k).”.

20 (e) SUNSET.—The amendment made by subsections
21 (a)(2) and (d)(1) to the extent that they relate to an ac-
22 credited person under section 712 of the Federal Food,
23 Drug, and Cosmetic Act shall be of no force or effect upon
24 the expiration of 7 years from the date of the enactment
25 of this Act.

1 **SEC. 10. CLASSIFICATION PANELS.**

2 Section 513(b) (21 U.S.C. 360c(b)) is amended by
3 adding at the end the following:

4 “(5) Classification panels covering each type of device
5 shall be scheduled to meet at such times as may be appro-
6 priate for the Secretary to meet applicable statutory dead-
7 lines.

8 “(6)(A) Any person whose device is specifically the
9 subject of review by a classification panel shall have the
10 same rights as the Secretary regarding—

11 “(i) the submission of written information to a
12 classification panel;

13 “(ii) the participation of the persons at meet-
14 ings of the panel; and

15 “(iii) access to data and information submitted
16 to a classification panel (except for data and infor-
17 mation that are not available for public disclosure
18 under section 552 of title 5, United States Code).

19 “(B) Any meetings of a classification panel shall pro-
20 vide adequate time for initial presentations and for re-
21 sponse to any differing views by persons whose devices are
22 specifically the subject of a classification panel review, and
23 shall encourage free and open participation by all inter-
24 ested persons.

25 “(7) Within 30 days after the date a classification
26 panel makes its conclusions and recommendations on any

1 matter under review by the panel, the Food and Drug Ad-
2 ministration official responsible for the matter shall review
3 the conclusions and recommendations of the panel, shall
4 make a final decision on the matter, and shall notify the
5 affected persons of the decision in writing and, if the deci-
6 sion differs from the conclusions and recommendations of
7 the panel, shall include the reasons for the difference.

8 “(8) A scientific advisory panel under this subsection
9 shall not be subject to the annual chartering and annual
10 report requirements of the Federal Advisory Committee
11 Act. Such a panel shall make an annual report of its ac-
12 tivities to the Secretary.”

13 **SEC. 11. PREMARKET APPROVAL.**

14 Section 515(d) (21 U.S.C. 360e(d)), as amended by
15 section 8(c)(2), is amended by redesignating paragraphs
16 (2), (3), (4), (5), and (6) as paragraphs (5), (6), (7), (8),
17 and (9), respectively, and by adding after paragraph (1)
18 the following:

19 “(2) Each application received under subsection (c)
20 shall be reviewed in a manner to achieve final action on
21 such application within 180 days of its receipt. The Sec-
22 retary shall meet with an applicant, at the request of the
23 applicant, under such an application within 90 days of the
24 date of the application’s submission.

1 “(3) On January 1 of each calendar year, the Sec-
2 retary shall submit to the Committee on Commerce of the
3 House of Representatives and the Committee on Labor
4 and Human Resources of the Senate a report summariz-
5 ing each instance in the previous fiscal year in which the
6 requirements of paragraph (2) were not met. This report
7 shall include reasons for the failures to meet the require-
8 ments of paragraph (2) and proposals to ensure that such
9 requirements will be met.”.

10 **SEC. 12. ACCREDITATION FOR ACCREDITED PERSONS.**

11 (a) AMENDMENT.—Subchapter A of chapter VII is
12 amended by adding at the end the following:

13 “ACCREDITED PERSONS

14 “SEC. 712. (a) IN GENERAL.—The Secretary shall,
15 within 1 year of the date of the enactment of this section,
16 accredit persons for the purpose of reviewing and initially
17 classifying devices under section 513(f)(1) that are subject
18 to a report under section 510(k). An accredited person
19 may not be used to perform a review of a class III device
20 or a class II device which is intended to be permanently
21 implantable or life sustaining or life supporting.

22 “(b) ACCREDITATION.—

23 “(1) PROGRAMS.—The Secretary shall provide
24 for such accreditation through programs adminis-
25 tered by the Food and Drug Administration, other

1 government agencies, or by other qualified non-
2 government organizations.

3 “(2) ACCREDITATION.—

4 “(A) GENERAL RULE.—Within 180 days
5 of the date of the enactment of this section, the
6 Secretary shall establish and publish in the
7 Federal Register requirements to accredit or
8 deny accreditation to persons who request to
9 perform the duties specified in subsection (a).
10 The Secretary shall respond to a request for ac-
11 creditation within 60 days of the receipt of the
12 request. The accreditation of such person shall
13 specify the particular activities under subsection
14 (a) for which such person is accredited.

15 “(B) WITHDRAWAL OF ACCREDITATION.—

16 The Secretary may withdraw accreditation of
17 any person accredited under this paragraph,
18 after providing notice and an opportunity for an
19 informal hearing, when such person acts or fails
20 to act in a manner that is inconsistent with the
21 purposes of this section or poses a threat to
22 public health.

23 “(C) PERFORMANCE AUDITING.—To en-
24 sure that persons accredited under this section

1 will continue to meet the standards of accredi-
2 tation, the Secretary shall—

3 “(i) make onsite visits on a periodic
4 basis to each accredited person to audit
5 the performance of such person; and

6 “(ii) take such additional measures as
7 the Secretary determines to be appropriate.

8 “(D) ANNUAL REPORT.—The Secretary
9 shall include in the annual report required
10 under section 903(e)(2) the names of all accred-
11 ited persons and the particular activities under
12 subsection (a) for which each such person is ac-
13 credited and the name of each accredited per-
14 son whose accreditation has been withdrawn
15 during the year.

16 “(3) QUALIFICATIONS.—An accredited person
17 shall, at a minimum, meet the following require-
18 ments:

19 “(A) Such person shall be an independent
20 organization which is not owned or controlled
21 by a manufacturer, supplier, or vendor of de-
22 vices and which has no organizational, material,
23 or financial affiliation with such a manufac-
24 turer, supplier, or vendor.

1 “(B) Such person shall be a legally con-
2 stituted entity permitted to conduct the activi-
3 ties for which it seeks accreditation.

4 “(C) Such person shall not engage in the
5 design, manufacture, promotion, or sale of de-
6 vices.

7 “(D) Such person shall be operated in ac-
8 cordance with generally accepted professional
9 and ethical business practices and shall agree in
10 writing that as a minimum it will—

11 “(i) certify that reported information
12 accurately reflects data reviewed;

13 “(ii) limit work to that for which com-
14 petence and capacity are available;

15 “(iii) treat information received,
16 records, reports, and recommendations as
17 proprietary information; and

18 “(iv) promptly respond and attempt to
19 resolve complaints regarding its activities
20 for which it is accredited.

21 “(4) SELECTION OF ACCREDITED PERSONS.—

22 The Secretary shall provide each person who chooses
23 to use an accredited person to receive a section
24 510(k) report a panel of at least 2 or more accred-

1 ited persons from which the regulated person may
2 select 1 for a specific regulatory function.”.

3 (b) CONFORMING AMENDMENT.—Section 301 (21
4 U.S.C. 321), as amended by section 7(b), is amended by
5 adding at the end the following:

6 “(y) in the case of a drug, device, or food—

7 “(A) the submission of a report or rec-
8 ommendation by a person accredited under section
9 712 that is false or misleading in any material re-
10 spect;

11 “(B) the disclosure by a person accredited
12 under section 712 of confidential commercial infor-
13 mation or any trade secret without the express writ-
14 ten consent of the person who submitted such infor-
15 mation or secret to such person; or

16 “(C) the receipt by a person accredited under
17 section 712 of a bribe in any form or the doing of
18 any corrupt act by such person associated with a re-
19 sponsibility delegated to such person under this
20 Act.”.

21 (c) SUNSET.—The amendments made by subsections
22 (a) and (b) to the extent they relate to an accredited per-
23 son under section 712 of the Federal Food, Drug, and
24 Cosmetic Act shall be of no force or effect upon the expira-

1 tion of 7 years from the date of the enactment of this
2 Act.

3 (d) REPORT.—Not later than 5 years after the date
4 of the enactment of this Act, the Secretary of Health and
5 Human Services shall report to the Committee on Com-
6 merce of the House of Representatives and the Committee
7 on Labor and Human Resources of the Senate on the use
8 of accredited persons under section 712 of the Federal
9 Food, Drug, and Cosmetic Act, the extent to which such
10 use was helpful in the implementation of such Act, and
11 the extent to which such use promoted actions which were
12 contrary to the purposes of such Act.

13 **SEC. 13. PREAMENDMENT DEVICES.**

14 Section 515(i) (21 U.S.C. 360e(i)) is amended to
15 read as follows:

16 “REVISION

17 “(i) Within 6 months of the date of the enactment
18 of the Medical Device Regulatory Modernization Act of
19 1997, the Secretary shall publish in the Federal Register
20 a list of the types of devices classified into class III under
21 section 513(d), which are not subject to a regulation under
22 section 515(B), and for which the Secretary has deter-
23 mined that premarket approval is unnecessary to protect
24 the public health. Each such type of device listed in the
25 Federal Register publication shall be regulated as a class

1 III device subject to the general controls under this Act
2 and appropriate special controls.”.

3 **SEC. 14. DEVICE TRACKING.**

4 Subsection (e) of section 519 (21 U.S.C. 360i) is
5 amended to read as follows:

6 “(e) DEVICE TRACKING.—The Secretary may by
7 order require a manufacturer to adopt a method of track-
8 ing a class II or class III device—

9 “(1) the failure of which would be reasonably
10 likely to have serious adverse health consequences;
11 and

12 “(2) which is—

13 “(A) intended to be an implantable device,

14 or

15 “(B) a life sustaining or life supporting de-
16 vice used outside a device user facility.”.

17 **SEC. 15. POSTMARKET SURVEILLANCE.**

18 Section 522 (21 U.S.C. 360l) is amended to read as
19 follows:

20 “POSTMARKET SURVEILLANCE

21 “SEC. 522. (a) IN GENERAL.—The Secretary may by
22 order require a manufacturer to conduct postmarket sur-
23 veillance for any device of the manufacturer which is a
24 class II or class III device the failure of which would be
25 reasonably likely to have serious adverse health con-
26 sequences and which is intended to be—

1 “(1) an implantable device, or

2 “(2) a life-sustaining or life-supporting device
3 used outside a device user facility.

4 “(b) SURVEILLANCE APPROVAL.—Each manufac-
5 turer required to conduct a surveillance of a device shall,
6 within 30 days of receiving an order from the Secretary
7 prescribing that the manufacturer is required under this
8 section to conduct such surveillance, submit, for the ap-
9 proval of the Secretary, a plan for the required surveil-
10 lance. The Secretary, within 60 days of the receipt of such
11 plan, shall determine if the person designated to conduct
12 the surveillance has appropriate qualifications and experi-
13 ence to undertake such surveillance and if such plan will
14 result in information necessary to determine the occur-
15 rence of unforeseen events. Any order requiring a prospec-
16 tive postmarket surveillance shall not require a surveil-
17 lance period greater than 18 months unless the Secretary
18 for public health concerns extends the period for an addi-
19 tional 18 months.”.

20 **SEC. 16. HARMONIZATION.**

21 (a) SECTION 520(f).—Section 520(f)(1)(B) (21
22 U.S.C. 360j(f)(1)(B)) is amended by striking “and” at the
23 end of clause (i), by striking the period at the end of
24 clause (ii) and inserting “; and” and by adding after
25 clause (ii) the following:

1 “(iii) ensure that such regulation conforms, to
2 the extent practicable, with the international stand-
3 ards organization standards defining quality sys-
4 tems, or parts thereof, for medical devices.”.

5 (b) SECTION 803.—Section 803 (21 U.S.C. 383) is
6 amended by adding at the end the following:

7 “(c)(1) The Secretary shall participate in meetings
8 with other countries to discuss methods and approaches
9 to reduce the burden of regulation, harmonize regulatory
10 requirements, and seek appropriate reciprocal arrange-
11 ments. The Secretary shall, within 180 days of the date
12 of enactment of this subsection, make public a plan that
13 establishes a framework for achieving mutual recognition
14 of good manufacturing practices.

15 “(2) The Secretary shall report to the Committee on
16 Commerce of the House of Representatives and the Com-
17 mittee on Labor and Human Resources of the Senate at
18 least 60 days before executing any bilateral or multilateral
19 agreement under paragraph (1).”.

20 **SEC. 17. REPORTS.**

21 (a) EXCLUSION OF REPORTS BY DISTRIBUTORS.—
22 Section 519 (21 U.S.C. 360i) is amended—

23 (1) in subsection (a), by striking “manufac-
24 turer, importer, or distributor” and inserting “man-
25 ufacturer or importer”;

1 (2) in paragraph (4) of subsection (a), by strik-
2 ing “manufacturer, importer, or distributor” and in-
3 serting “manufacturer or importer”;

4 (3) in paragraph (8) of subsection (a), by strik-
5 ing “manufacturer, importer, or distributor” each
6 place it occurs and inserting “manufacturer or im-
7 porter”;

8 (4) in subsection (a), by inserting “and” at the
9 end of paragraph (7), by striking “; and” at the end
10 of paragraph (8) and inserting a period, and by
11 striking paragraph (9).

12 (b) REGULATIONS.—Within 120 days after the date
13 of enactment of this section, the Secretary of Health and
14 Human Services shall delete the regulations of the Sec-
15 retary appearing in part 804 of title 21 of the Code of
16 Federal Regulations, requiring distributors, other than
17 importers, to make reports of deaths, serious injuries or
18 illness, and malfunctions related to devices.

19 (c) CERTIFICATIONS, AND REPORTS OF REMOVALS
20 AND CORRECTIONS.—Section 519 (21 U.S.C. 360i) is
21 amended by striking subsections (d) and (f).

22 (d) DESIGNATED DEVICE USER FACILITIES.—Sec-
23 tion 519(b) (21 U.S.C. 360i(b)) is amended—

24 (1) by redesignating paragraphs (2) through
25 (5) as paragraphs (3) through (6), respectively;

1 (2) by striking “(b)(1)(A) Whenever a device
2 user facility receives” and inserting the following:

3 “(b)(1) One year after the date of the enactment of the
4 Medical Device Regulatory Modernization Act of 1997,
5 regulations included in title 21, Code of Federal Regula-
6 tions, pertaining to user reporting shall be deemed to be
7 rescinded by the Secretary. On and after such date, there
8 shall be no obligations for any device user facility to com-
9 ply with this subsection until the Secretary promulgates
10 regulations which limit user reporting to a subset of hos-
11 pitals and nursing homes to create a representative profile
12 of user reports for device deaths and serious illnesses or
13 serious injuries.

14 “(2)(A) Whenever a designated device user facility re-
15 ceives”;

16 (3) in paragraph (2) (as designated by para-
17 graph (2) of this subsection)—

18 (A) in subparagraph (B), in the matter
19 preceding clause (i), by inserting “designated”
20 before “device user facility”;

21 (B) in subparagraph (C)—

22 (i) in the first sentence—

23 (I) by inserting “designated” be-
24 fore “device user facility”; and

1 (II) by striking “a semi-annual
2 basis” and inserting “an annual
3 basis”;

4 (ii) in the second sentence, by striking
5 “and July 1”; and

6 (iii) by striking the matter after and
7 below clause (iv); and

8 (C) in subparagraph (D), by inserting
9 “designated” before “device user facility”;

10 (4) in each of paragraphs (3) through (5) (as
11 redesignated by paragraph (1) of this subsection), by
12 striking “paragraph (1)” each place such term ap-
13 pears and inserting “paragraph (2)”; and

14 (5) in paragraph (6) (as redesignated by para-
15 graph (1) of this subsection)—

16 (A) by redesignating subparagraph (B) as
17 subparagraph (C); and

18 (B) by inserting after subparagraph (A)
19 the following:

20 “(B) The term ‘designated device user facility’
21 means a hospital or a nursing home that is des-
22 igned as a member of the subset established by the
23 Secretary for purposes of paragraph (1).”.

1 **SEC. 18. G.M.P. AND DEVICE REPORTS.**

2 Section 303(c) (21 U.S.C 333(c)) is amended by in-
3 serting before the period at the end the following: “; or
4 (6) for having violated subsection (a), (b), (c), or (k) of
5 section 301 by failure to comply with either section
6 502(t)(2) or 501(h), or for having violated section
7 301(q)(1)(B) by failing to furnish material or information
8 required under section 519(a), if such person acted in
9 good faith, had no reason to believe that the person’s acts
10 violated the law, and had no prior notice from the Sec-
11 retary that the acts constituted violations of the Act”.

12 **SEC. 19. INFORMATION SYSTEM.**

13 Chapter IX is amended by adding at the end the fol-
14 lowing:

15 **“SEC. 906. INFORMATION SYSTEM.**

16 “The Secretary shall establish and maintain an infor-
17 mation system to track the status and progress of each
18 application or submission (including a petition, notifica-
19 tion, or other similar form of request) submitted to the
20 Food and Drug Administration requesting agency action.
21 The system shall permit access by the applicant.”.

22 **SEC. 20. ENVIRONMENTAL IMPACT REVIEW.**

23 Chapter VII is amended by adding at the end the
24 following:

1 “SUBCHAPTER D—ENVIRONMENTAL IMPACT REVIEW

2 **“SEC. 741. ENVIRONMENTAL IMPACT REVIEW.**

3 “No action by the Secretary proposed to be taken
4 pursuant to this Act shall require the preparation of an
5 environmental assessment or environmental impact state-
6 ment under the National Environmental Policy Act of
7 1969 unless the Secretary finds that because of extraor-
8 dinary circumstances the proposed action may have a sig-
9 nificant effect, either directly or cumulatively, on the
10 human environment.”.

11 **SEC. 21. PRACTICE OF MEDICINE.**

12 Chapter IX, as amended by section 19, is amended
13 by adding at the end the following:

14 **“SEC. 907. PRACTICE OF MEDICINE.**

15 “Nothing in this Act shall be construed to limit or
16 interfere with the authority of a health care practitioner,
17 licensed by law to administer drugs and devices, to pre-
18 scribe or administer any legally marketed drug or device
19 to a patient for any condition or disease within a legiti-
20 mate health care practitioner-patient relationship.”.

21 **SEC. 22. PUBLICATION OF NOTICE OF DEVIATION.**

22 Section 705 (21 U.S.C 375) is amended by adding
23 at the end the following:

24 “(c) The Secretary may make public or communicate
25 to any person outside the Food and Drug Administration

1 any information regarding a notice which informs a regu-
2 lated person of a purported deviation from a requirement
3 of this Act only after the Secretary has completed the in-
4 vestigation of such deviation, except as provided in sub-
5 section (b).”.

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